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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,793	03/18/2004	Erik Buntinx	29248/21	5618

1912 7590 11/10/2009

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EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
11/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,793	BUNTINX, ERIK	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,50,54,55,72,92 and 93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *50,55,92 and 93* is/are allowed.

6)☒ Claim(s) *49,54 and 72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3pgs (8/18/09)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/18/09 has been entered.

Applicants' arguments, filed 08/18/09, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claim 49 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of PERMAX® prescribing information (http://www.fda.gov/medwatch/safety/2003/permax_PI.pdf, revised October 2, 2003, pp. 1-2) and Kuhajda et al (US 5,759,837).

Applicants maintain the assertion that Muller teaches against combining pipamperone and PD drugs. Applicant then cites additional art which teaches the combination "ordinarily should not be administered concurrently" and that it “may be expected" that anti-psychotics block the function of dopamine-agonists. Applicants also

assert that the dosage of pipamperone is significantly lower than conventional dosages. Applicants assert Müller is related to treatment of various Parkinson-associated disorders or symptoms, but does not teach treatment of Parkinson per se. Finally, Applicants appear to assert unexpected results where a related patent application demonstrates the in vitro and in vivo effect.

Examiner disagrees. While the prior art does raise caution about co-administration, the prior art does not teach against the combination of active agents. Again, where the prior art uses terms like “ordinarily should not” and “may be expected” suggests there may be instances where such results do not occur. As previously discussed by Examiner, there may be situations where the risks involved may outweigh the teaching, leading the skilled artisan to combine treatments.

Second, while Applicants argue the dosage from of pipamperone is significantly lower than conventional dosages, examiner now also cites Kuhajda et al (US 5,759,837) to show that the state of the art at the time of the invention, the skilled artisan would routinely administer low dosages of components and work the dosage up when testing for optimal dosage (see Kuhajda et al US 5,759,837 col 17 lines 38-59). Thus, the skilled artisan would have reasonably have tested both dosage forms from a sub-therapeutic level and increased the amount to maximum tolerance, finding the optimal amount of pipamperone to administer.

Third, with respect to the treatment, when treating a disorder, it would be obvious to not only treat the disorder itself, but also treat the symptoms thereof, given the symptoms are used to define the disorder. Thus, the skilled artisan would recognize

treating both Parkinson-per se and treating the associated disorders or symptoms caused by the same would be treating the same condition, i.e. Parkinson's with associated disorders or symptoms.

Finally, where Applicants assert unexpected results of improved effectiveness of the dopamine receptor agonist, Examiner agrees that where the standard dosage of the active agents when administered with a low dose of pipamperone results in lowered side effects, as demonstrated in the related patent applications 2005/0203130 at paragraphs 775-885, where the Working Examples demonstrate the reduced side effects of the primary reference. But the instantly rejected claims are not commensurate in scope with the showing, given the rejected claims are not directed a specific dosage of the dopamine receptor agonist. Thus, where the dosage of the dopamine receptor agonist is decreased, there would likewise be an expectation of lowered side effects.

Claim 54 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of Silver et al. (Neurology, 1998, Vol. 50, Suppl. 6, pp. S18-S22).

Because Applicants did not specifically address this rejection, this rejection is maintained for the reasons stated above.

Claim 72 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Müller (Expert Opinion on Pharmacotherapy, 2002, Vol. 3, No 4, pp. 381-388) in view of Nystrom et al. (US 5,6345,213).

Because Applicants did not specifically address this rejection, this rejection is maintained for the reasons stated above.

Allowable subject matter

Claims 50, 55, 92, and 93 are allowed because the dopamine agonists and dosage amounts thereof are limited in scope to the showing of unexpected results by Applicant, thus overcoming the 103 rejection above for these embodiments. Note, these claims differ from the rejected claims in that the rejected claims either do not define limit the dopamine receptor agonist or do not define the dosage amount.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612